REMARKS

Drawings

The Drawings were objected to under 37 CFR 1.83(a). The Examiner asserts that the drawings must show every feature of the invention specified in the claims. Therefore, he asserts that the delivery source with a separable element such as a bladder or patch must be shown or the feature cancelled from the claim(s). Applicants respectfully submit that the proposed corrected drawings and amendment to the specification overcome this objection. The amendments do not add new matter.

Fig. 10 does not add new matter. The subject matter of Fig. 10 is fully described and supported by the discussion of **an element that is separate from the jacket of the device**, for example, such as a bladder or patch, at least at pages 34 and 35. One of skill in the art, having read the specification, especially at page 34, line 29 through page 35, line 28 could readily determine that the disclosure describes the subject matter of the proposed Fig. 10. The amendments to pages 34 and 35 merely serve to clarify that the "**element that is separate from the jacket of the device,**" such as a patch or bladder, can be referred to as a "separable element."

Rejection under 35 U.S.C. §112, second paragraph

Claims 3, 7, and 8 were rejected under 35 U.S.C. §112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, claim 3 recites the limitation "an external geometry" in line 19, for which the Examiner asserts there is insufficient antecedent basis. Applicants respectfully submit that claim 1, on which claim 3 is dependent does have sufficient antecedent basis for the assertion of "an external geometry". Specifically, line 7 of claim 1 refers to "an external geometry of the heart".

Specifically, claim 7 recites the limitation "one or more therapeutic agents" in line 29, for which the Examiner asserts there is insufficient antecedent basis. Applicants respectfully submit that claim 1, on which claim 7 is dependent does have sufficient antecedent basis for the assertion of "one or more therapeutic agents". Specifically, lines 11 and 12 refer to "one or more therapeutic agents".

Specifically, claim 8 recites the limitation "one or more therapeutic agents" in lines 1 and 2, for which the Examiner asserts there is insufficient antecedent basis. Applicants respectfully submit that claim 1, on which claim 8 is dependent does have sufficient antecedent basis for the assertion of "one or more therapeutic agents". Specifically, lines 11 and 12 refer to "one or more therapeutic agents".

Based on the above comments, Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. § 103

Claims 1-22 were rejected under 35 U.S.C. § 103(a) as unpatentable over Girard (US 6,174,279). Applicants respectfully traverse this rejection.

Applicants respectfully assert that Girard cannot properly be asserted in a rejection under 35 U.S.C. § 103. Amendments to 35 U.S.C. § 103, in which subsection c was added and which became effective November 29, 1999 state that "subject matter developed by another person, which qualifies as prior art only under subsection (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." 35 U.S.C. § 103(c).

Michael Girard is the inventor of the subject matter disclosed in US 6,174,279. The subject matter of the present application was invented by Robert Walsh, J. Edward Shapland, Donald Rohrbaugh, and Donald Palme. Therefore, US 6,174,279 and the present application have different inventive entities, and are therefore developed by another according to MPEP § 2136.04.

US 6,174,279 was assigned to Acorn Cardiovascular, as has been recorded by the United States Patent and Trademark Office at reel 010268, frame 0703. Furthermore, the subject matter of the pending application when developed was subject to an obligation to assign to Acorn Cardiovascular, and indeed was assigned thereto, as is evidenced by the recordation of the assignment at reel 011191, frame 0739.

Based on the above, US 6,174,279 cannot be used in a rejection of the present application under 35 U.S.C. § 103. Withdrawal of this rejection is therefore respectfully requested.

The Examiner also rejects claims 1-22 under 35 U.S.C. § 103(a) as being unpatentable over Girard in view of Altman. As asserted above, Girard cannot properly be utilized in a rejection of this application under 35 U.S.C. § 103.

Alone, the disclosure of Altman does not render the invention obvious. The device of Altman is not located on the heart, it is a delivery system that is positioned and configured so that it delivers therapeutic agents into the heart. Specifically, devices and methods for drug delivery with devices implanted into the chest, including a drug delivery catheter with a tip for implantation into the heart wall and a drug reservoir implanted into the chest. Furthermore, the devices of Altman require pumps to input the therapeutic agents into the heart.

In order to establish *prima facie* obviousness, three basic criteria must be met, namely: (1) there must be some suggestion or motivation to combine the references or modify the reference teaching; (2) there must be a reasonable expectation of success; and (3) the reference or references when combined must teach or suggest each claim limitation. Applicants submit that the Office Action failed to state a *prima facie* case of obviousness, and therefore the burden has not properly shifted to Applicants to present evidence of nonobviousness.

Applicants respectfully assert that Altman does not render the claimed invention obvious because it neither teaches nor suggests a jacket as recited in the claimed invention. Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn in view of the above comments.

CONCLUSION

In view of the amendments and remarks presented herein, it is respectfully submitted that the claims are in condition for allowance and notification to that effect is earnestly solicited.

Respectfully submitted,

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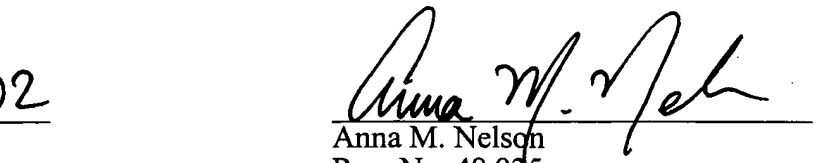

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MARKED UP VERSION TO SHOW CHANGES MADE

IN THE SPECIFICATION

At page 5, line 4 please insert the following:

--Fig. 10 is a schematic cross sectional view of an embodiment of a cardiac reinforcement device according to the invention, including a separable element.--

At page 34 and 35, please replace the paragraph spanning lines 29 of page 34 and lines 7 of page 35 with the following:

-- In another embodiment of the present invention, the delivery source is provided as an element that is separate from the jacket 10 of the device, herein referred to as a "separable element" 36. The [delivery source] separable element 36 can be provided in the form of a patch containing the therapeutic agent of interest, or a bladder containing the therapeutic agent. Suitable patches and bladders are known in the art. For example, see Epicardial Administration of Ibutilide from Polyurethane matrixes: Effects on Defibrillation Threshold and Electrophysiologic Parameters, Labhasetwar et al., J. Of Cardiovascular Pharm., 24:826-840 (1994), Sotalol Controlled-Release Systems for Arrhythmias: In Vitro Characterization, In Vivo Drug Disposition, and Electrophysiologic Effects, Labhasetwar et al., J. of Pharm. Sciences, 83: 156-164 (1994).--

At page 35, please replace the paragraph spanning lines 12 to 24 with the following:

In this embodiment, an example of which is depicted in Fig. 10, the jacket provides an anchoring surface for the [delivery source] separable element 36 that presses the [delivery source] separable element 36 against the surface of the heart and maintains the [delivery source] separable element 36 in position on the heart H. According to the invention, the patch or bladder can be provided underneath the jacket 10, such that the [delivery source] separable element 36 is positioned between the jacket and the heart. The jacket presses the [delivery source] separable element 36 against the heart, without causing damage to the heart that would result from directly

attaching the [source] separable element 36 at the treatment site, by sutures, adhesives or the like. The [delivery source] separable element 36 can be attached to the jacket, for example, using sutures or bioadhesives, to maintain the position of the [delivery source] separable element 36 in relation to the jacket. Alternatively, the patch or bladder can be held in place simply by the pressure of the jacket against the heart. Because the jacket itself is maintained in non-shifting contact with the heart, the [delivery source] separable element 36 is also provided with a non-shifting position on the surface of the heart. For example, the use of the jacket to maintain the positioning of the [delivery source] separable element 36 avoids such undesirable effects as fibrosis, necrosis, and the like.